UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to_____

Commission file number: 001-41031

Bluejay Diagnostics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**47-3552922**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
360 Massachusetts Avenue, Suite 203, Acton, MA	**01720**
(Address of Principal Executive Offices)	(Zip Code)

(844) 327-7078
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging Growth Company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	BJDX	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The registrant had 1,023,345 shares of common stock outstanding at August 4, 2023.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this Quarterly Report on Form 10-Q (this "Form 10-Q"). In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or "continue," and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this Form 10-Q may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Form 10-Q to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Form 10-Q in the case of forward-looking statements contained in this Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

EXPLANATORY NOTE

In this Form 10-Q, and unless the context otherwise requires, the "Company," "we," "us," and "our" refer to Bluejay Diagnostics, Inc. and its wholly owned subsidiary Bluejay SpinCo, LLC, taken as a whole.

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

Bluejay Diagnostics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,100,407	$ 10,114,990
Prepaid expenses and other current assets	1,481,512	1,673,480
Total current assets	6,581,919	11,788,470
Property and equipment, net	1,464,125	1,232,070
Operating lease right-of-use assets	400,609	465,514
Other non-current assets	31,675	35,211
Total assets	$ 8,478,328	$ 13,521,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 271,488	$ 635,818
Operating lease liability, current	168,713	168,706
Accrued expenses and other current liabilities	1,392,378	835,730
Total current liabilities	1,832,579	1,640,254
Operating lease liability, non-current	255,306	323,915
Other non-current liabilities	14,104	15,823
Total liabilities	2,101,989	1,979,992
Commitments and Contingencies (See Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value; 7,500,000 shares authorized; 1,023,345 and 1,010,764 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	102	101
Additional paid-in capital	28,726,487	28,538,274
Accumulated deficit	(22,350,250)	(16,997,102)
Total stockholders' equity	6,376,339	11,541,273
Total liabilities and stockholders' equity	$ 8,478,328	$ 13,521,265

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

Bluejay Diagnostics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ -	$ 249,040	$ -	$ 249,040
Cost of sales	-	200,129	-	200,129
Gross profit	-	48,911	-	48,911
Operating expenses:				
Research and development	1,676,256	756,283	3,030,805	1,451,040
General and administrative	1,073,103	1,196,996	2,250,080	2,516,815
Sales and marketing	154,329	81,357	302,375	135,042
Total operating expenses	2,903,688	2,034,636	5,583,260	4,102,897
Operating loss	(2,903,688)	(1,985,725)	(5,583,260)	(4,053,986)
Other income:				
Other income, net	90,383	48,323	230,112	103,181
Total other income, net	90,383	48,323	230,112	103,181
Net loss	$ (2,813,305)	$ (1,937,402)	$ (5,353,148)	$ (3,950,805)
Net loss per share - Basic and diluted	$ (2.75)	$ (2.00)	$ (5.24)	$ (2.00)
Weighted average common shares outstanding:				
Basic and diluted	1,023,052	1,007,115	1,020,865	1,007,115

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

Bluejay Diagnostics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2022	**1,010,764**	**$ 101**	**$ 28,538,274**	**$ (16,997,102)**	**$ 11,541,273**
Stock-based compensation expense	-	-	54,730	-	54,730
Grants of fully vested restricted stock units to settle accrued bonus, net of shares withheld	12,188	1	107,234	-	107,234
Net loss	-	-	-	(2,539,843)	(2,539,843)
Balance at March 31, 2023	**1,022,953**	**$ 102**	**$ 28,700,238**	**$ (19,536,945)**	**$ 9,163,395**
Stock-based compensation expense	-	-	27,702	-	27,702
Issuance of common stock	750	-	-	-	-
RSU tax withholding	(358)	-	(1,453)	-	(1,453)
Net loss	-	-	-	(2,813,305)	(2,813,305)
Balance at June 30, 2023	1,023,345	$ 102	$ 28,726,487	**$ (22,350,250)**	$ 6,376,339

	Stockholders' Equity				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2021	**1,005,612**	**$ 101**	**$ 28,076,394**	**$ (7,694,786)**	**$ 20,381,709**
Impact of adoption of ASC 842	-	-	-	(5,368)	(5,368)
Stock-based compensation expense	-	-	126,086	-	126,086
Exercise of common stock Series B Warrants	1,950	-	-	-	-
Net loss	-	-	-	(2,013,403)	(2,013,403)
Balance at March 31, 2022	**1,007,562**	**$ 101**	**$ 28,202,480**	**$ (9,713,557)**	$ 18,489,024
Stock-based compensation expense	-	-	106,114	-	106,114
Exercise of common stock Series B Warrants	55		-	-	-
Net loss	-	-	-	(1,937,402)	(1,937,402)
Balance at June 30, 2022	**1,007,617**	**$ 101**	**$ 28,308,594**	**$ (11,650,959)**	$ 16,657,736

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

Bluejay Diagnostics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (5,353,148)	$ (3,950,805)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	373,192	83,792
Stock-based compensation expense	247,293	232,200
Amortization of right-of-use asset	80,655	66,972
Impairment of property and equipment	1,787	-
Changes in operating assets and liabilities:		
Inventory	-	(671,250)
Prepaid expenses and other current assets	191,968	575,563
Other non-current assets	3,536	(14,056)
Accounts payable	(429,590)	(99,670)
Due to related party	-	(2,000)
Accrued expenses and other current liabilities	472,980	242,937
Net cash used in operating activities	**(4,411,327)**	**(3,536,317)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(541,774)	(169,599)
Net cash used in investing activities	**(541,774)**	**(169,599)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of tax withholding obligations on restricted stock units	(59,079)	-
Payment of finance lease	(2,403)	-
Net cash used in financing activities	**(61,482)**	**-**
Decrease in cash and cash equivalents	(5,014,583)	(3,705,916)
Cash and cash equivalents, beginning of period	10,114,990	19,047,778
Cash and cash equivalents, end of period	$ 5,100,407	$ 15,341,862
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH FINANCING ACTIVITIES		
Liabilities incurred for the purchase of property and equipment	$ 65,260	$ -

See notes to unaudited condensed consolidated financial statements.

Bluejay Diagnostics, Inc.
Notes to the Condensed Consolidated Financial Statements
(Unaudited)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. ("Bluejay" or the "Company") is a medical diagnostics company developing rapid tests using whole blood on our Symphony technology platform ("Symphony") to improve patient outcomes in critical care settings. The Company's Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP that consists of a mobile device and single-use test cartridges that if cleared, authorized, or approved by the U.S. Food and Drug Administration (the "FDA"), can provide a solution to a significant market need in the United States. Clinical trials indicate the Symphony device produces laboratory-quality results in less than 20 minutes in intensive care units and emergency rooms, where rapid and reliable results are required.

Bluejay's first product, the Symphony IL-6 test, is for the monitoring of disease progression in critical care settings. IL-6 is a clinically established inflammatory biomarker, considered a 'first-responder,' for assessment of severity of infection and inflammation across many disease indications, including sepsis. A current challenge of healthcare professionals is the excessive time and cost associated determining a patient's level of severity at triage and the Symphony IL-6 test has the ability to consistently monitor this critical care biomarker with rapid results.

In the future, Bluejay plans to develop additional tests for Symphony including two cardiac biomarkers (hsTNT and NT pro-BNP), as well as other tests using the Symphony platform. The Company does not yet have regulatory clearance for its Symphony products, and its Symphony products will need to receive regulatory authorization from the FDA in order to be marketed as a diagnostic product in the United States.

Bluejay's operations to date have been funded primarily through the proceeds of the Company's initial public offering (the "IPO") in November 2021 (the "IPO Date").

On June 4, 2021, the Company formed Bluejay Spinco, LLC, a wholly owned subsidiary of the Company, for potential further development of the Company's ALLEREYE diagnostic test. ALLEREYE is a point-of-care device offering healthcare providers a solution for diagnosing Allergic Conjunctivitis.

FDA Regulatory Strategy

The Company's current regulatory strategy is designed to support commercialization of Symphony in the United States pending marketing authorization from the FDA. The Company has shifted its focus away from COVID-19 patients due to a significant decline in the number of COVID-19 related hospitalizations. Based on this revised strategy, the Company plans to conduct a clinical study to support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. The Company submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on August 11, 2023. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, the Company intends to proceed as planned while taking into account the FDA's feedback. The Company believes that it will maintain the previously disclosed Symphony IL-6 regulatory submission timeline of the first half of 2024.

The Company has targeted large, well-known medical and academic institutions for its study, which the Company believes will help support initial commercialization and market penetration. The Company believes that this clinical trial expansion could also support additional indications, but that any such expansion also could delay obtaining marketing authorization for the product. Based on the pre-submission meeting with the FDA, the focus of the clinical trial will be the risk stratification of hospitalized sepsis patients.

The Company maintains contracts with Toray Industries, Inc ("Toray") to manufacture our cartridges and Sanyoseiko Co. Ltd ("Sanyoseiko") to manufacture both our device and cartridges.

Risks and Uncertainties

As noted above, Bluejay is reliant upon Toray and Sanyoseiko to provide cartridges in sufficient quantity and quality to complete our clinical trials, and our clinical trials could be delayed if the Company encountered any material supply interruptions while the clinical trials are being conducted. In addition, there can be no assurance that we will be able to obtain necessary regulatory authorization for the manufacturing or marketing of the Symphony in the United States or elsewhere. There also can be no assurance that we will successfully complete any clinical evaluations necessary to receive regulatory approvals, or that the clinical trial will demonstrate sufficient safety and efficacy of the Symphony. The failure to adequately demonstrate the clinical performance of the Symphony device could delay or prevent regulatory approval of the device, which could prevent or result in delays to market launch and could materially harm our business.

In addition to the FDA regulatory strategy risks and uncertainties, the Company is subject to a number of risks similar to other companies in its industry, including rapid technological change, competition from larger biotechnology companies and dependence on key personnel. The Company is also impacted by inflationary pressures and global supply chain disruptions currently impacting many companies.

On October 25, 2022, the Company received a notification letter from the Nasdaq Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that the closing bid price for its common stock had been below $1.00 for the previous 30 consecutive business days and that the Company therefore is not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). On April 25, 2023, at the Company's request, Nasdaq's Listing Qualifications Staff notified the Company that it has extended the time for the Company to regain compliance with the Minimum Bid Requirement until October 23, 2023. To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 or higher for a minimum of ten consecutive business days.

On July 24, 2023, the Company executed a reverse stock split of its shares of common stock at a ratio of 1-for-20 (the "Reverse Stock Split"), with a corresponding reduction in the number of authorized outstanding number of shares of common stock from 100,000,000 to 7,500,000. The Reverse Stock Split became effective on July 24, 2023, when the Company's common stock opened for trading on The Nasdaq Capital Market on a post-split basis under the Company's existing trading symbol, "BJDX." At such time, the Company's common stock also commenced trading with a new CUSIP number, 095633301.

On August 8, 2023, the Company received a letter from the Listing Qualifications Department of Nasdaq notifying the Company that, based on the closing bid price of the Company's common stock having been at least $1.00 per share for the required period, the Company has regained compliance with Nasdaq Listing Rule 5550(a)(2) and the minimum bid price deficiency matter previously disclosed by the Company on October 25, 2022 is now closed.

All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-20 reverse stock split.

Going Concern

The Consolidated Financial Statements for the interim periods ended June 30, 2023 and 2022 were prepared under the assumption that the Company will continue as a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. However, the Company has incurred net losses since its inception, and has negative cash flows from operations and will need additional funding to complete planned development efforts. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company had cash and cash equivalents of $5.1 million as of June 30, 2023. It continues to develop the Symphony device and its first test for the measurement of IL-6. It remains committed to obtaining FDA clearance and will conduct clinical trials to obtain sufficient data to support its FDA submission, while also continuing to build its manufacturing operations with its contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining its liquidity requirement; as well as $1.8 million of current liabilities on its balance sheet as of June 30, 2023 and commitments of approximately $1.9 million as of June 30, 2023 (see Notes 8 and 9). The Company estimates cash resources will be sufficient to fund its operations into the fourth quarter of 2023. The Company will need additional capital to fund its planned operations for the next 12 months.

The Company expects that it will seek to raise such additional capital through public or private equity offerings, grant financing and support from governmental agencies, convertible debt, collaborations, strategic alliances and distribution arrangements. Additional funds may not be available when it needs them on terms that are acceptable to them, or at all. If adequate funds are not available, it may be required to delay its FDA regulatory strategy, and to delay or reduce the scope of its research or development programs, its commercialization efforts or its manufacturing commitments and capacity. In addition, if it raises additional funds through collaborations, strategic alliances or distribution arrangements with third parties, it may have to relinquish valuable rights to its technologies or future revenue streams.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in conformity with generally accepted accounting principles in the United States ("US GAAP") consistent with those applied in, and should be read in conjunction with, the Company's audited financial statements and related footnotes for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K. The unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2023 and December 31, 2022, its results of operations and cash flows for the three and six months ended June 30, 2023 and 2022, in accordance with US GAAP. The unaudited condensed consolidated financial statements do not include all of the information and footnotes required by US GAAP for complete financial statements, as allowed by the relevant U.S. Securities and Exchange Commission ("SEC") rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

The results for the three and six months ended June 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023, or any other interim period within this fiscal year.

2. SIGNIFICANT ACCOUNTING POLICIES

During the six months ended June 30, 2023, there were no changes to the significant accounting policies as described in the 2022 Audited Financial Statements.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in these condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in accounting for the fair value-based measurement of stock-based compensation, accruals, and warrants. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the condensed consolidated financial statements.

Stock-based compensation

Share-based compensation expense for all share-based payment awards made to employees, directors and non-employees is measured based on the grant-date fair value of the award. Share-based compensation expense for awards granted to non-employees is determined using the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. The Company recognizes the compensation cost of share-based awards on a straight-line basis over the requisite service period. For stock awards for which vesting is subject to performance-based milestones, the expense is recorded over the implied service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved.

The Company recognizes forfeitures related to employee share-based payments when they occur. Forfeited options are recorded as a reduction to stock compensation expense.

Research and development expenses

Costs incurred in the research and development of new products are expensed as incurred. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, fees for professional service providers and costs associated with product development efforts, including preclinical studies and clinical trials.

The Company estimates preclinical study and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf.

Segment Reporting

Management has determined that the Company has one operating segment, which is consistent with the Company structure and how it manages the business.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury stock and if-converted methods. Dilutive common stock equivalents are comprised of convertible preferred stock, convertible notes, options outstanding under the Company's stock option plan and warrants. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares):

	June 30,	
	2023	**2022**
Options to purchase common stock	35,858	40,290
Restricted stock units	9,875	-
Warrants for common stock	40,594	40,594
Class A warrants for common stock	124,200	124,200
Class B warrants for common stock	3,770	3,825

Recently Adopted Accounting Standards

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers ("ASU 805")*, an amendment of the ASC. The amendments to ASU 805 address diversity and inconsistency related to the recognition and measurement of contract assets and contract liabilities acquired in a business combination and require that an acquirer recognize and measure contract assets and contract liabilities acquired in accordance with ASC 2014-09, *Revenue from Contracts with Customers (Topic 606) (*"ASC 606"). Under GAAP, an acquirer generally recognizes assets and liabilities assumed in a business combination, including contract assets and liabilities arising from revenue contracts with customers, at fair value on the acquisition date. ASU No. 2021-08 will result in the acquirer recording acquired contract assets and liabilities on the same basis that would have been recorded by the acquiree before the acquisition under ASC 606. The Company adopted this new standard on January 1, 2023. The new standard had no impact on the Company's consolidated statements of operations or cash flows.

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

On October 6, 2020, the Company entered into a License and Supply Agreement ("License Agreement") with Toray Industries, Inc. ("Toray"). Under the License Agreement, the Company received the exclusive license (outside of Japan) to make and distribute protein detection cartridges that have a function of automatic stepwise feeding of reagent (the "Cartridges"). In addition, following the first sale of the Cartridges after regulatory approval, the Company will make royalty payments to Toray equal to 15% of the net sales of the Cartridges for the period that any underlying patents exist or five years after the first sale. Following the first sale after obtaining regulatory approval, the Company will make minimum annual royalty payments of $60,000 for the first year and $100,000 for each year thereafter, which shall be creditable against any royalties owed to Toray in such calendar year. There were no sales of or revenues from the Cartridges during the six-month periods ended June 30, 2023 and 2022.

As of June 30, 2023 and December 31, 2022, there were no amounts accrued related to the License Agreement.

4. WARRANTS

The following table summarizes information with regard to warrants outstanding as of June 30, 2023:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
Common Stock Warrants	40,594	Common Stock	$ 64.80	2.6
Class A Warrants	124,200	Common Stock	$ 140.00	3.3
Class B Warrants	3,770	Common Stock	$ 200.00[1]	3.3

1 Class B Warrants may also exercise such warrants on a “cashless” basis. See Class A Warrants and Class B Warrants subsection below.

No warrants were issued during the three and six months ended June 30, 2023 and 2022.

Class A Warrants and Class B Warrants

In conjunction with the Company’s IPO in November 2021 the Company issued 108,000 Class A Warrants and 108,000 Class B Warrants. Additionally, the underwriter of the IPO exercised their overallotment option, solely with respect to the Class A Warrants and Class B Warrants, shortly after the IPO Date resulting in an additional issuance of 16,200 Class A Warrants and 16,200 Class B Warrants. From the net IPO proceeds, $5,164,751 and $7,323,161, respectively, were apportioned to the Class A Warrants and Class B Warrants.

Class A Warrants entitle the holder to purchase one share of common stock at an exercise price of $140.00 per share. As of June 30, 2023 and 2022 all Class A Warrants were outstanding.

Class B Warrants entitle the holder to purchase one share of common stock at an exercise price of $200.00 per share. Holders of Class B Warrants may also exercise such warrants on a “cashless” basis after the earlier of (i) 10 trading days from closing date of the offering or (ii) the time when $10.0 million of volume is traded in the Company’s common stock, if the volume weighted average price of the Company’s common stock on any trading day on or after the closing date of the offering fails to exceed the exercise price of the Class B Warrant (subject to adjustment as described in the warrant agreement). During the six months ended June 30, 2023, no Class B Warrants were exercised, while during the six months ended June 30, 2022, 2,005 Class B Warrants were exercised, all on a cashless basis. As of June 30, 2023 and 2022, there were 3,770 Class B Warrants outstanding.

5. STOCK COMPENSATION

Stock Incentive Plans

In 2018, the Company adopted the 2018 Stock Incentive Plan (the “2018 Plan”) for employees, consultants, and directors. The 2018 Plan, administered by the Board of Directors, permits the Company to grant incentive and nonqualified stock options for the purchase of common stock and restricted stock awards. The maximum number of shares reserved for issuance under the 2018 Plan is 31,472. As of June 30, 2023, there were 13,113 shares available for grant under the 2018 Plan.

On July 6, 2021, the Company’s board of directors and stockholders approved and adopted the Bluejay Diagnostics, Inc. 2021 Stock Plan (the “2021 Plan”). A total of 98,000 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. As of June 30, 2023, there were 40,377 shares available for grant under the 2021 Plan.

Stock Award Activity

The following table summarizes the status of the Company's non-vested restricted stock awards for the six months ended June 30, 2023:

	Non-vested Restricted Stock Awards	
	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	3,000	$ 25.80
Granted	25,609	8.80
Vested	(19,484)	9.45
Forfeited	(750)	25.80
Outstanding at June 30, 2023	8,375	$ 11.84

In February 2023, the Company issued 18,734 fully vested restricted stock units to certain employees as a portion of their 2022 bonuses.

The following is a summary of stock option activity for the six months ended June 30, 2023:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2022	35,992	$ 39.25	6.5	$ 20,578
Granted	1,000	10.60		
Exercised	-	-		
Cancelled and forfeited	(1,133)	64.00		
Outstanding at June 30, 2023	35,858	$ 37.67	7.4	$ 9,531
Exercisable at June 30, 2023	28,222	$ 37.22	7.1	$ 9,531

The weighted average grant date fair value of options granted during the six months ended June 30, 2023 and 2022 was $8.80 per share and $28.33 per share, respectively. The Company calculated the grant-date fair value of stock option awards granted during the six months ended June 30, 2023 and 2022 using the Black-Scholes model with the following assumptions:

	Six Months Ended June 30,	
	2023	2022
Risk-free interest rate	3.63%	1.58% – 3.06%
Expected dividend yield	0.00%	0.00%
Volatility factor	108.78%	102.03% - 104.40%
Expected life of option (in years)	6.00	5.37 – 6.00

Stock-Based Compensation Expense

For the three and six months ended June 30, 2023 and 2022, the Company recorded stock-based compensation expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 151	$ 16,392	$ 44,996	$ 33,704
General and administrative	28,662	89,562	188,246	197,866
Sales and marketing	(1,110)	160	14,050	630
Total stock-based compensation	$ 27,703	$ 106,114	$ 247,292	$ 232,200

As of June 30, 2023, there was $64,426 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 1.4 years. As of June 30, 2023, there was $56,881 of unrecognized compensation expense related to non-vested restricted stock awards that are expected to be recognized over a weighted-average period of 0.9 years.

6. RELATED PARTY TRANSACTIONS

NanoHybrids, LLC

In December 2021, the Company entered into an agreement with NanoHybrids, LLC ("NanoHybrids") to utilize the Company's research and development staff and laboratory facility when available to perform work for NanoHybrids. Any hours worked by Company employees for NanoHybrids is billed to NanoHybrids at a bill rate of the respective employee's fully burdened personnel cost plus 10%. Additionally, the Company may purchase certain lab supplies for NanoHybrids and rebill these costs to NanoHybrids. NanoHybrids is wholly owned by the Company's Chief Technology Officer. The table below summarizes the amounts earned and due from NanoHybrids as of and for the three- and six-month periods' ended June 30, 2023 and 2022, and balances due as of June 30, 2023 and December 31, 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Income from NanoHybrids included in Other Income	$ 40,975	$ 35,040	$ 136,773	$ 75,926
Cash receipts from NanoHybrids	$ 136,773	$ 18,347	$ 156,504	$ 40,886

	As of	
	June 30, 2023	December 31, 2022
Amounts receivable from NanoHybrids included in Prepaids and Other Current Assets	$ -	$ 19,731

7. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at June 30, 2023 and December 31, 2022:

	Depreciable lives	June 30, 2023	December 31, 2022
Construction-in-process		$ 956,389	$ 375,466
Furniture, fixtures, and equipment	3-5 years	141,164	136,942
Software	3-5 years	4,457	4,457
Lab equipment	3-5 years	1,287,783	1,268,380
Leasehold improvements	Shorter of useful life or lease term	43,231	43,231
		2,433,024	1,828,476
Less: accumulated depreciation		(968,899)	(596,406)
Property and equipment, net		$ 1,464,125	$ 1,232,070

The Company reviews long-lived assets for impairment when events, expectations, or changes in circumstances indicate that the asset's carrying value may not be recoverable. As a result of this review in 2023, the Company revised the useful life of certain lab equipment in the first quarter of 2023 due to a change in expectations of the time the equipment will be used which resulted in approximately $247,000 of additional depreciation recorded in the six months ended June 30, 2023.

8. LEASES

The Company primarily enters into lease arrangements for office and laboratory space. A summary of supplemental lease information is as follows:

	Six Months Ended	
	June 30, 2023	June 30, 2022
Weighted average remaining lease term – operating leases (in years)	3.3	4.1
Weighted average remaining lease term – finance leases (in years)	4.6	-
Weighted average discount rate	7.0%	7.0%
Operating cash flows from operating leases	$ 84,352	$ 71,421
Operating cash flows from finance leases	$ 2,403	-

A summary of the Company's lease assets and liabilities are as follows:

	June 30, 2023	December 31, 2022
Operating lease right-of-use asset	$ 400,609	$ 465,514
Finance lease asset – property & equipment, net	21,067	21,067
Total lease assets	421,676	486,581
Current portion of operating lease liability included in accrued expenses	168,713	168,706
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Non-current operating lease liabilities	255,306	323,915
Non-current finance lease liabilities included in other non-current liabilities	14,103	15,823
Total lease liabilities	$ 442,928	$ 513,251

A summary of the Company's estimated operating lease payments are as follows:

Year	
2023 (1)	$ 84,354
2024	162,991
2025	100,000
2026	100,000
2027	25,000
Thereafter	-
Total future lease payments	472,345
Less: Imputed interest	48,326
Present value of lease liability	$ 424,019

(1) Excludes the six months ended June 30, 2023

9. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company had, as of June 30, 2023, open, non-cancelable purchase commitments with its primary contract manufacturing organization (CMO) of $383,000 for manufacturing line development and $580,000 for initial production units. The Company also had $416,000 of other non-cancelable purchase commitments for research and development supplies and key advisory services.

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of Cartridges, the Company will also make royalty payments to Toray equal to 15% of the net sales of the Cartridges for the period that any underlying patents exist or for 5 years after the first sale. Following the first sale, the Company will pay a one-time minimum royalty of $60,000, which shall be creditable against any royalties owed to Toray in such calendar year. The Company will pay a minimum royalty of $100,000 in each year thereafter, which are creditable against any royalties owed to Toray in such calendar year. There were no sales of or revenues from the Cartridges through June 30, 2023.

Indemnification

The Company has certain agreements with service providers with which it does business that contain indemnification provisions pursuant to which the Company typically agrees to indemnify the party against certain types of third-party claims. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. The Company would also accrue for estimated incurred but unidentified indemnification issues based on historical activity. As the Company has not incurred any indemnification losses to date, there were no accruals for or expenses related to indemnification issues for any period presented.

10. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	June 30, 2023	December 31, 2022
Prepaid insurance	$ 352,436	$ 751,979
Vendor prepayments	950,607	681,218
Prepaid other	178,469	240,283
Total prepaid expenses and other current assets	$ 1,481,512	$ 1,673,480

Accrued expenses and other current liabilities consist of the following:

	June 30, 2023	December 31, 2022
Accrued personnel costs	$ 568,350	$ 533,577
Accrued good receipts	100,249	10,077
Accrued other	723,779	292,076
Total accrued expenses and other current liabilities	$ 1,392,378	$ 835,730

11. SUBSEQUENT EVENTS

On July 24, 2023, the Company executed a reverse stock split of its shares of common stock at a ratio of 1-for-20, with a corresponding reduction in the number of authorized outstanding number of shares of common stock from 100,000,000 to 7,500,000. All of the Company’s historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-20 reverse stock split.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Form 10-Q. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Form 10-Q.

Overview

We are a clinical-stage medical diagnostics company developing rapid tests using whole blood on our Symphony platform ("Symphony") to improve patient outcomes in critical care settings. Our Symphony technology platform is an exclusively licensed, patented system that consists of a mobile device and single-use test cartridges that if cleared, authorized, or approved by the U.S. Food and Drug Administration ("FDA"), can provide a solution to a significant market need in the United States. Clinical trials indicate Symphony produces laboratory-quality results in less than 20 minutes in intensive care units and emergency rooms, where rapid and reliable results are required.

Since inception, we have incurred net losses from operations each year and we expect to continue to incur losses for the foreseeable future. We incurred net losses of $5.3 million and $2.8 million for the six months ended June 30, 2023 and 2022, respectively. We had negative cash flow from operating activities of approximately $4.4 million and $3.5 million for the six months ended June 30, 2023 and 2022, respectively, and had an accumulated deficit of approximately $22.4 million as of June 30, 2023.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2023 and 2022

The following table sets forth our results of operations for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ -	$ 249,040	$ -	$ 249,040
Cost of sales	-	200,129	-	200,129
Gross Profit	-	48,911	-	48,911
Operating expenses:				
Research and development	1,676,256	756,283	3,030,805	1,451,040
General and administrative	1,073,103	1,196,996	2,250,080	2,516.815
Sales and marketing	154,329	81,357	302,375	135,042
Total operating expenses	2,903,688	2,034,636	5,583,260	4,102,897
Operating loss	(2,903,688)	(1,985,725)	(5,583,260)	(4,053,986)
Other income				
Other income, net	90,383	48,323	230,112	103,181
Total other income, net	90,383	48,323	230,112	103,181
Net loss	$ (2,813,305)	$ (1,937,402)	$ (5,252,148)	(3,950,805)

Revenue and Gross Profit

Revenue and gross profit decreased approximately $249,000 and $49,000 respectively, for the three- and six-month periods ended June 30, 2023, as compared to the same periods in 2022. The decrease was due to a minor sale of five Symphony analyzers to our business partner, Toray during 2022. Future sales to Toray after 2022 were not anticipated.

Research and Development

Research and development expenses for the three and six months ended June 30, 2023 were approximately $1.7 million and $3.0 million, respectively, as compared to approximately $756,000 and $1.5 million, respectively, for the comparable periods in 2022. The increase in research and development expenses was primarily due to an increase in personnel costs and product development expenses. We expect future research and development expenses to be focused on our clinical trial program and any necessary manufacturing improvements.

General and Administrative

General and administrative expenses for the three and six months ended June 30, 2023 were approximately $1.1 million and $2.3 million, respectively, as compared to approximately $1.2 million and $2.5 million, respectively, for the comparable periods in 2022. The minor decrease in general and administrative expenses is due to continued efforts to preserve capital by limiting our investment in infrastructure commensurate with our commercialization timeline. We expect to monitor and continue to pare our general and administrative spend, as necessary, to optimize operational alignment.

Sales and Marketing

Sales and marketing expenses for the three and six months ended June 30, 2023 were approximately $154,000 and $302,000, respectively, as compared to approximately $81,000 and $135,000, respectively, for the comparable periods in 2022. The increase in sales and marketing expenses was primarily due to increased personnel costs.

Other Income, net

Other income, net for the three and six months ended June 30, 2023 was approximately $90,000 and $230,000 as compared to approximately $48,000 and $103,000 for the same periods in 2022. The increase in net other income was primarily due to higher interest rates and an increase in related party income from NanoHybrids, as compared to the comparative three- and six-month periods.

Liquidity and Going Concern

We have funded our operations primarily through the net proceeds from our IPO on November 10, 2021. We had cash and cash equivalents of $5.1 million as of June 30, 2023. We continue to develop the Symphony device and its first cartridge for the measurement of IL-6. We remain committed to obtaining FDA clearance and will conduct clinical trials to obtain sufficient data to support our FDA submission, while also continuing to build our manufacturing operations with our contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining our liquidity requirement; as well as $1.8 million of current liabilities on our balance sheet as of June 30, 2023 and commitments of approximately $1.9 million as of June 30, 2023 (see Notes 8 and 9). As of the filing of this report, we expect to need additional capital to fund our planned operations for the next twelve months.

We expect that we will seek to raise such additional capital through public or private equity offerings, grant financing and support from governmental agencies, convertible debt, collaborations, strategic alliances and distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay our FDA regulatory strategy, and to delay or reduce the scope of our research or development programs, our commercialization efforts or our manufacturing commitments and capacity. In addition, if we raise additional funds through collaborations, strategic alliances or distribution arrangements with third parties, we may have to relinquish valuable rights to its technologies or future revenue streams.

If we are unsuccessful in our efforts to raise additional capital, based on our current and expected levels of operating expenses, our current capital will not be sufficient to fund our operations for the next twelve months. These conditions raise substantial doubt about our ability to continue as a going concern.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented.

	Six Months Ended June 30,	
	2023	2022
Cash proceeds (used in) provided by:		
Operating activities	$ (4,411,327)	$ (3,536,317)
Investing activities	(541,774)	(169,599)
Financing activities	(61,482)	-
Net decrease in cash and cash equivalents	$ (5,014,583)	$ (3,705,916)

Net cash used in operating activities

During the six months ended June 30, 2023, we used approximately $4.4 million in cash for operating activities, an increase of approximately $875,000 million as compared to approximately $3.5 million for the same period in 2022. The increase in net cash used in operating activities was primarily due to increases in personnel and product development costs.

Net cash used in investing activities

During the six months ended June 30, 2023, we used approximately $542,000 in cash for investing activities, an increase of approximately $372,000 as compared to the same period in 2022. The increase in net cash used in investing activities was primarily due to capital purchases of manufacturing equipment.

Net cash used in financing activities

During the six months ended June 30, 2023, we used approximately $61,000 in cash for financing activities, an increase of approximately $61,000 as compared to the same period in 2022. The increase in net cash used in financing activities was primarily due to shares withheld to cover tax withholdings on restricted stock units vested during the period.

Recently Adopted Accounting Standards

See Note 2 to our condensed consolidated financial statements (under the caption “Recently Adopted Accounting Standards”).

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We are using the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (ii) the date on which we have issued more than $1 billion in non-convertible debt securities during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

JOBS Act Accounting Election

The JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We have implemented all new accounting pronouncements that are in effect and may impact our financial statements and we do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as Amended (the "Exchange Act") and are not required to provide the information required under this item.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures and Changes in Internal Control over Financial Reporting

We conducted an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), regarding the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of June 30, 2023. We continue to review our disclosure controls and procedures and may from time to time make changes aimed at enhancing their effectiveness and ensuring that our systems evolve with our Company's business. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

(b) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We are not able to estimate an aggregate amount or range of reasonably possible losses for those legal matters for which losses are not probable and estimable. We have insurance policies covering potential losses where such coverage is cost effective.

We are not at this time involved in any legal proceedings.

Item 1A. Risk Factors

For a discussion of potential risks or uncertainties, see “Risk Factors” in the Company’s 2022 annual report on Form 10-K on file with the SEC. Except as set forth below, there have been no material changes to the risk factors disclosed in such registration statement.

We recently determined to adapt our clinical trial design to obtain more patient data to reflect recent FDA feedback, and our regulatory pathway remains subject to further FDA review and feedback and the results of future clinical studies.

Our current regulatory strategy is designed to support commercialization of Symphony in the United States pending marketing authorization from the FDA. We have shifted our focus away from COVID-19 patients due to a significant decline in the number of COVID-19 related hospitalizations. Based on this revised strategy, we plan to conduct a clinical study to support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. We submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on August 11, 2023. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, we intend to proceed as planned while taking into account the FDA’s feedback. We believe that we will maintain the previously disclosed Symphony IL-6 regulatory submission timeline of the first half of 2024.

We have targeted large, well-known medical and academic institutions for our study, which we believe will help support initial commercialization and market penetration. We believe that this clinical trial expansion could also support additional indications, but that any such expansion also could delay obtaining marketing authorization for the product. Based on the pre-submission meeting with the FDA, the focus of the clinical trial will be the risk stratification of hospitalized sepsis patients.

Although we believe that we have a sound strategy for obtaining FDA regulatory approval and clearance, there can be no assurance that it will ultimately be obtained. Reasons that approval and clearance might not be obtained, on our expected timeline or at all, include that we are unable to complete our planned studies (due to lack of funding, delays or interruptions in the manufacturing of quality-sufficient cartridges needed to be used in the study, or otherwise), that clinical results are not sufficient to demonstrate required efficacy, or that the FDA does not agree with our study design or aspects of our submission. In addition, the FDA could also change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which could prevent or delay approval or clearance. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description
10.1	First Amendment to Employment Agreement, entered into and effective as of January 27, 2023, between Bluejay Diagnostics, Inc. and Neil Dey (initially filed as Exhibit 10.1 on Form 8-K (File No. 001-41031) on January 27, 2023, and incorporated by reference herein).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(1)	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

(1) The certifications on Exhibit 32 hereto are deemed not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Bluejay Diagnostics, Inc.

SIGNATURE	TITLE	DATE
/s/ Neil Dey Neil Dey	Chief Executive Officer and Director (on behalf of the registrant)	August 14, 2023
/s/ Kenneth Fisher Kenneth Fisher	Chief Financial Officer (principal financial and accounting officer)	August 14, 2023

Exhibit 31.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER

I, Neil Dey, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bluejay Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 14, 2023

By: /s/ Neil Dey
Neil Dey
Chief Executive Officer
(Principal executive officer)

Exhibit 31.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER

I, Kenneth Fisher, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bluejay Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 14, 2023

By: /s/ Kenneth Fisher
Kenneth Fisher
Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Bluejay Diagnostics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended June 30, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 14, 2023

By: /s/ Neil Dey
Neil Dey
Chief Executive Officer
(Principal executive officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Bluejay Diagnostics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended June 30, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 14, 2023

By: /s/ Kenneth Fisher
Kenneth Fisher
Chief Financial Officer
(Principal financial and accounting officer)